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REMARKS/ ARGUMENTS

Applicant has carefully studied the nonfinal Examiner's Action mailed June 27, 2007, having a shortened statutory period for response set to expire September 27, 2007. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by Office, to ensure full response on the merits to each finding of Office.

Claim Rejections - 35 U.S.C. § 112

Claims 11, 13, and 18 stand rejected for indefiniteness, under 35 U.S.C. § 112, paragraph two. The second paragraph of 35 U.S.C. § 112 requires a specification to conclude with at least one claim enumerating the subject matter of the claimed invention.¹ Further the claims must be clear and precise.² Office states that claims 11, 13, and 18 do not enunciate the subject matter of the particular claim.³ Applicant has cancelled claim 13, rendering rejection of that claim moot.

Office found claims 11 and 18 fail to identify what solution the term "milliliter" referred.⁴ Applicant has amended the claims to include the term "of administered umbilical cord blood composition."

Applicant respectfully believes the changes to claims 11 and 18, and the cancellation of claim 13, along with the response hereto, address the concerns enunciated by Office. Accordingly, it is respectfully requested that the 35 U.S.C. § 112 rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1-4, 6-10, and 12-16 stand rejected under 35 U.S.C. § 102(a), as being anticipated by Dengler, et al. (Herz 2000, 7: 598-610). Additionally, Office has rejected claims 1 and 11 under 35 U.S.C. § 102(b) as anticipated by Chen, et al. (Stroke 2001, 2682- 2688) in light of Lim, et al. (Bone Marrow Transplantation 1999, 24:965-970). Applicant has cancelled claims 2, 4, and 13, rendering rejections on those claims moot.

¹ MPEP 2171.

² MPEP 2173.02.

³ See, Office Action, dated June 27, 2007, page 2.

⁴ Office Action, dated June 27, 2007, page 2.

Every element of the claim must be found in a single prior art reference for an application to be rejected for anticipation.⁵ Further, the prior art must enable, or describe, "the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention[.]"⁶ without undue experimentation⁷. Further, the invention must carry out the same function.⁸

Claims 1-4, 6-10, and 12-16, 35 U.S.C. § 102(a)

Applicant acknowledges Office's rejection of claims 1-4, 6-10, and 12-16 under 35 U.S.C. § 102(a), as being anticipated by Dengler, et al. (Herz 2000, 7: 598-610). Office stated that Dengler teaches a treatment method for myocardial infarction through administration of umbilical cord blood cells directly into the heart tissue or systemically.⁹ Dengler does discuss administering umbilical cord blood cells for treating myocardial infarction, but does not provide any information on the administration of umbilical cord blood cells, the amount of cells needed, or any other information¹⁰, other than to state "experimental studies of cord blood stem cells for cardiac replacement therapy ... seem warranted."¹¹ Therefore, Dengler fails to provide any information which would enable one, of ordinary skill in the art, to carry out the invention. Additionally, Dengler states that

the largest obstacle against the successful use of human embryonic stem cells to replace heart muscle will be the tissue incompatibility on the level of the HLA system.¹²

Dengler further states that "umbilical cord stem cells ... show few differences compared with embryonic stem cells regarding the use for cardiac regeneration[.]"¹³ Hence, Dengler teaches that human umbilical cord blood, to which Dengler limits its discussion, currently cannot replace human heart tissue. The reference must do more than merely name or describe the subject matter.¹⁴

⁵ See, MPEP 2131, citing Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

⁶ Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., 468 F.3d 1366, 1383 (Fed. Cir. 2006).

⁷ MPEP 2121.01.

⁸ National Business Systems, Inc. v. AM Intern., Inc., 743 F.2d 1227, 1235 (7th Cir. 1981) (Quoting Popell Bros., Inc. v. Schick Electric, Inc., 494 F.2d 162, 164 (7th Cir. 1974)).

⁹ Office Action, dated June 27, 2007, page 3.

¹⁰ See, T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 2, lines 18-43.

¹¹ T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 2, lines 35-39.

¹² T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 1, lines 17-20.

¹³ T. Dengler, H. Katus, "Stem Cell Therapy for the Infarcted Heart ("Cellular Cardiomyoplasty")," Herz 7:598-610, 2002, page 604, column 2, lines 24-29..

¹⁴ MPEP 2121.01.

Dengler does not provide information in carrying out circulatory or cardiac disease treatment, such that an individual skilled in the art would be capable of treating a patient with umbilical cord blood cells. Therefore, the elements of independent claim 1 and independent claim 12 are not covered in a single reference, and claims 1 and 12 cannot be anticipated. As such, the claims dependent on claims 1 and 12 are also patentable. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 6-10, 12, and 14-16 be withdrawn.

Claims 1 and 11, 35 U.S.C. § 102(b)

Office has rejected claims 1 and 11 under 35 U.S.C. § 102(b), as being anticipated by Chen, et al. (Stroke 2001, 2682-2688) in light of Lim (Bone Marrow Trans., 1999, 24:965-970). Applicant has cancelled claims 2, 4, and 13, rendering rejections on those claims moot.

Every element of the claim must be found in a single prior art reference for an application to be rejected for anticipation.¹⁵ Further, multiple references may only be used to anticipate an invention to "prove the primary reference contains an "enabling disclosure," explain the meaning of a term used in the primary reference; or show that a characteristic not disclosed in the reference is inherent."¹⁶

Claim 1 recites "a method of treating a circulatory disorder[.]" Chen teaches administering umbilical cord blood cells after stroke to reconstitute an ischemic brain microenvironment.¹⁷ But, Chen does not discuss cardiac damage or the utility of umbilical cord blood for treating cardiac damage or disorders. As such, Chen does not recite every element of claim 1, and cannot anticipate claim 1. Office then contends Lim discloses the missing elements of Chen, by disclosing that umbilical cord blood contains large quantities of white blood cells.¹⁸ However, like Chen, Lim does not disclose the use of umbilical cord blood cells to treat cardiac disorders. As such, because neither Chen, nor Chen along with Lim, disclose all elements of claim 1, the cited references do not anticipate claim 1. Further, as claim 1 is not anticipated, all claims dependent on claim 1, including claim 11, are also not anticipated, as a matter of law. Accordingly, it is respectfully requested that the rejection of claims 1 and 11 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

¹⁵ Sec. MPEP 2131, citing Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

¹⁶ MPEP 2131.01.

¹⁷ Jieli Chen, Paul Sanberg, et al., "Intravenous Administration of Human Umbilical Cord Blood Reduces Behavioral Deficits After Stroke in Rats", *Stroke*, 2682-2688, 2682, column 2, 2001.

¹⁸ Office Action, dated June 27, 2007, page 4.

Applicant acknowledges Office has rejected claims 5, 11, 17, and 18 under 35 U.S.C. § 103(a), as being unpatentable.

To support a rejection under 35 USC §103(a), a *prima facie* case of obviousness must be made.¹⁹ As such, the prior art must suggest or motivate an individual in the art to modify or combine the references, a reasonable expectation of success must be present, and the teaching must teach or suggest all the claim limitations.²⁰

Office has rejected claims 5, 11, 17, and 18 in light of Dengler et al., in view of Broxmeyer et al. (Proc. Nat. Acad. Sci., 1992, 89:4109-4113), Lim et al., (Bone Marrow Trans., 1999, 24:965-970), Anversa (US Pub.No. 2002/0061587 A1), and Edelberg, et al. (US Pub.No. 2003/0091547 A1).²¹

Applicant respectfully traverses Office's rejection as Dengler, Broxmeyer, Lim, and Edelberg do not teach the current invention and are not analogous art, and thus not prior art for the purposes of 35 U.S.C. § 103(a).²²

Dengler does not teach the current invention, as, Dengler does not provide any enabling disclosure to allow an individual skilled in the art to practice the invention, as discussed *supra*. Dengler does teach the need for the current invention, but fails to teach how to get to the current invention. Dengler does not discuss combining Broxmeyer, Lim, and Anversa. A *prima facie* case must show the obviousness of the current invention, not the obviousness to try.²³

Moreover, claims 5 and 11 are dependent to claim 1, and claims 17 and 18 are dependent to claim 12. As independent claims 1 and 12 are patentable, dependent claims 5, 11, 17, and 18 are also patentable as a matter of law. Therefore, it is respectfully requested that Office reconsider claims, 11, 17, and 18 and withdraw the rejection under 35 U.S.C. § 103(a).

¹⁹ MPEP 2143.

²⁰ See, MPEP 2143.

²¹ Office Action, dated June 27, 2007, page 5.

²² MPEP 2141.01(a)(I), (II) require the prior art to be analogous, meaning "either in the field of applicant's endeavor or, ... reasonable pertinent to the particular problem," relying on differences and similarities in structure and function.

²³ *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

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Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

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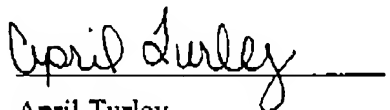
Dated: September 27, 2007

CERTIFICATE OF MAILING

(37 C.F.R. 1.8 (a))

I HEREBY CERTIFY that this Amendment A, is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 1651, Attn: Tayoon Kim, (571) 273-8300, on September 27, 2007.

Dated: September 27, 2007


April Turley